

25 June 1997

Subject: Guidelines for Use of Specimens Stored in the DoD Serum Repository
(DoDSR)

1. Purpose: There are NOT “blanket rules” that regulate uses of stored serologic specimens. All proposed uses must be evaluated on an individual basis. This SOP provides guidelines for uses of serologic specimens stored in the DoD Serum Repository (DoDSR).

2. Procedures:

a. Serum specimens linked to individuals:

i. Medical research:

(1) DoD: Stored sera (when linked to individual identifiers) may be used for medical research when formal reviews of written protocols assure scientific merit and protection of the rights of human research subjects. In general, studies that maintain links between serum specimens and individual identifiers will require the explicit informed consent of each research subject. The DoDSR will not release serum specimens for research purposes without copies of –

(a) the approval of the cognizant and duly constituted institutional review committee; and

(b) the approved protocol (with all appropriate investigator/collaborator signatures and institutional approvals).

(2) Non-DoD: Sera may be released for medical research by civilian investigators when the study has a DoD coinvestigator (who is

knowledgeable, responsible, and accountable for all aspects of the study's design and execution). Protocols by civilian investigators must have approvals (i.e., scientific and human use) of the cognizant institutional review boards of BOTH the principal investigator and the DoD coinvestigator.

ii. Individual patient care:

(1) DoD: Stored sera may be used by attending physicians in the military health system (MHS) for the specific purpose of evaluating or treating individual patients. In such cases, stored sera may be delivered to the attending physician without the explicit consent of the patient (i.e., the consent of the patient to use his/her serum for his/her care is assumed). Included under this circumstance is the use of patient serum to determine his/her immunologic susceptibility to vaccine preventable diseases – in order to determine the need for immunization(s).

(2): Non-DoD: Stored sera may be used by attending physicians outside the MHS for the specific purpose of evaluating or treating individual patients. In such cases, stored sera may be delivered to the attending physician **WITH THE EXPLICIT SIGNED INFORMED CONSENT OF THE PATIENT**. In this case, an MHS physician (in the same specialty as the requestor) should coordinate the request and validate the clinical relevance of the proposed use.

iii. Military medicine/community preventive care (“public health”):

(1) Sera linked to identifiers may be used (without the explicit informed consent of individuals) for the purpose of characterizing the nature, magnitude, and distribution of a specific medical threat to a defined military (or MHS beneficiary) population. The use is only

authorized when the primary *a priori* purpose is to define an *immediate* course of action in a *defined population*, e.g., outbreak investigation.

(2) If proposed uses for “public health” are likely to generate information potentially beneficial to individuals in the subject population (e.g., results indicative of a treatable condition), then there must be a plan for providing that information and acting upon it (e.g., counseling). The plan for handling and acting upon individual results must be approved by the medical authority responsible for the health care of the subject population PRIOR TO RELEASE OF THE SPECIMENS.

b. Serum specimens not linked to individuals:

i. Medical research:

(1) DoD: Stored sera (not linked to individual identifiers) may be used for medical research when formal reviews of written protocols assure scientific merit and protection of rights of human research subjects. If the link between serum specimens and individual identifiers is destroyed prior to the delivery of specimens to the investigators (i.e., investigators cannot link results to individuals), then individual informed consent is generally not required. The DoDSR will not release serum specimens for research purposes without copies of –

(a) the approval of the cognizant and duly constituted institutional review committee; and

(b) the approved protocol (with all appropriate investigator/collaborator signatures and institutional approvals).

(2) Non-DoD: Sera may be released for medical research by civilian investigators when the study has a DoD coinvestigator (who is knowledgeable, responsible, and accountable for all aspects of the study's design and execution). Protocols by civilian investigators must have approvals (i.e., scientific and human use) of cognizant institutional review boards of BOTH the principal investigator and the DoD coinvestigator.

ii. Individual patient care: Not applicable.

iii. Military medicine/community preventive care ("operational support"): Sera unlinked to identifiers may be used for general purposes of assessing -- and tracking over time -- the concentration, distribution, and determinants of medically relevant conditions (e.g., susceptibility to vaccine-preventable diseases) in defined military (or MHS beneficiary) populations. The use is authorized when, for example, the primary *a priori* purpose is to develop or measure effects of population based, military preventive medicine/public health policies (e.g., deployment-specific immunizations, booster intervals for military vaccines, geographic-specific threat assessments).

3. Administrative.

a. Authority: The Chief, Army Medical Surveillance Activity (AMSA), is solely responsible for authorizing release of specimens from the DoDSR. The chief, AMSA, is responsible to ensure that the specifications of this SOP are adhered to prior to authorizing the release of any specimens.

b. Physical protection of privacy:

i. Serum specimens in the DoDSR will be labeled with specimen numbers only.

- ii. DoDSR personnel will not be informed of or granted access to linkages between specimen numbers and individual identifiers (i.e., name, SSN).
- iii. DoDSR personnel will not append individual identifiers (i.e., name, SSN) to specimens.

c. Costs: Users of specimens will transfer funds to the AMSA to cover costs associated with maintaining the serum repository and associated data bases; identifying potentially useful specimens; locating, retrieving, apportioning, and delivering required specimens (with appropriate documentation); and re-archiving unused portions.